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APPLICATION NO.	_	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/882,945	06/15/2001		Victor Lyamichev	FORS-04586	9139
23535	7590	04/09/2004		EXAMINER	
MEDLEN &		,	MYERS, CARLA J		
SUITE 350					PAPER NUMBER
SAN FRANCISCO, CA 94105				1634	-
				DATE MAILED: 04/09/2004	ļ

Please find below and/or attached an Office communication concerning this application or proceeding.

			48 4				
	Application No.	Applicant(s)					
	09/882,945	LYAMICHEV ET	AL.				
Office Action Summary	Examiner	Art Unit	1.5				
	Carla Myers	1634	, , , , , , , , , , , , , , , , , , ,				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet w	vith the correspondence a	ddress				
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a within the statutory minimum of thi will apply and will expire SIX (6) MO cause the application to become A	a reply be timely filed irty (30) days will be considered time DNTHS from the mailing date of this ABANDONED (35 U.S.C. § 133).	ely. communication.				
Status							
1) Responsive to communication(s) filed on							
,	action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merit							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Discovitive of OL 1							
Disposition of Claims	•						
4) Claim(s) <u>1-43</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdray	vn from consideration.						
5) Claim(s) <u>1-26</u> is/are allowed.							
6)⊠ Claim(s) <u>15 and 27-43</u> is/are rejected.							
7) Claim(s) <u>15,27 and 43</u> is/are objected to.							
8) Claim(s) are subject to restriction and/or	election requirement.	÷,	**				
Application Papers							
9)☐ The specification is objected to by the Examine	r (i)	*					
10) The drawing(s) filed on is/are: a) acce		by the Evaminer					
Applicant may not request that any objection to the							
Replacement drawing sheet(s) including the correcti	• • • • • • • • • • • • • • • • • • • •		:FR 1 121(d)				
11) The oath or declaration is objected to by the Ex	· ·	- · ·					
		74 011100 7 1011011 01 101111 1					
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:	priority under 35 U.S.C.	§ 119(a)-(d) or (f).					
1. Certified copies of the priority documents	s have been received.		•				
2. Certified copies of the priority documents	s have been received in a	Application No					
3. Copies of the certified copies of the prior	ity documents have been	n received in this Nationa	ıl Stage				
application from the International Bureau	(PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of	of the certified copies no	t received.					
Attachment(s)		*					
1) Notice of References Cited (PTO-892)		Summary (PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	(s)/Mail Date Informal Patent Application (PT	(O 152)					
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/13/03</u> .	6) Other:		O-102)				
							

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DETAILED ACTION

1. The allowability of claims 1-43 is withdrawn. As indicated in the letter of March 31, 2004, prosecution in this application is being re-opened. Upon further consideration, the following grounds of rejection are being applied. This action is made non-final.

Claim Objections

2. Claims 15, 27 and 43 are objected to because the claims do not properly depend from claims 1, 16 and 28, respectively, since a claim to a product can not depend from a method of using a product. As set forth in MPEP 608.01(n), the test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. The test is not whether the claims differ in scope. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim. In the present case, the dependent claims to compositions comprising a probe do not require every limitation of the parent method claims and the claims to the compositions can be infringed upon without infringing the subject matter of the methods.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-43 are indefinite over the recitation of "wherein said length of said amplification products provides a distance of an accessible site on said target nucleic

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acid from said first domain" because it is unclear as to what is intended to be encompassed by this phrase. In particular, it is unclear as to what is intended to be meant by "a distance of an accessible site" and it is unclear as to how this distance is to be used to determine the location of the accessible site. For example, it is unclear as to whether this phrase refers to the length of the accessible site, the distance from the end of the amplification product to the beginning or end of the accessible site or the distance between the end/beginning of the extension primer and the end/beginning of the first domain or the end/beginning of the region that the second amplification primer binds to in the first domain.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Britschgi et al (U.S. Patent No. 5,770,373; June 23, 1998).

The claims are drawn to compositions comprising an oligonucleotide wherein the oligonucleotide comprises a sequence of a first region of a primer selected by the claimed methods for identifying primers and compositions comprising oligonucleotides which comprise a region complementary to an accessible site identified by the claimed methods. Thereby, the claims include compositions comprising oligonucleotides which are complementary to accessible sites. The method steps recited in claims 1, 16 and 28

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are not "read-into" the composition claims and these method steps do not further define any specific structural features of the oligonucleotides.

Britschgi et al teach compositions comprising oligonucleotides which specifically hybridize to regions of RNA that do not contain secondary structure (see, for example, Tables 2-5; column 14, lines 1-14; and column 26, lines 29-32). As such, the primers of Britschgi are complementary to accessible regions of target RNA. For example, at column 29, Britschgi teaches an oligonucleotide MTB030, which is complementary to a region of M. tuberculosis RNA that consists of a single-stranded region (as opposed to the MTB034 oligonucleotide which binds to a region of double-stranded RNA). Britschgi also teaches amplification of RNA using the oligonucleotides to the accessible regions (see, for example, column 31). Accordingly, Britschgi teaches compositions comprising oligonucleotides complementary to accessible regions, and these accessible regions are the same as those which could be identified by the present methods of claims 1, 16 and 28.

5. Claims 15, 27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (U.S. Patent No. 5,846723; December 8, 1998).

The claims are drawn to compositions comprising an oligonucleotide wherein the oligonucleotide comprises a sequence of a first region of a primer selected by the claimed methods for identifying primers and compositions comprising oligonucleotides which comprise a region complementary to an accessible site identified by the claimed methods. Thereby, the claims include compositions comprising oligonucleotides which are complementary to accessible sites. The method steps recited in claims 1, 16 and 28

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are not "read-into" the composition claims and these method steps do not further define any specific structural features of the oligonucleotides.

Kim et al teach compositions comprising oligonucleotides which specifically hybridize to regions of RNA that are accessible and do not contain secondary structure (see, for example, Table II; column 15, lines 13-41; and column 21, the first paragraph of "Example 2"). As such, the primers of Kim are complementary to accessible regions of target RNA. Kim teaches methods for identifying accessible regions of RNA using an RNase H cleavage reaction and teaches making oligonucleotides that are complementary to the identified accessible regions. Accordingly, Kim teaches compositions comprising oligonucleotides complementary to accessible regions, and these accessible regions are considered to be the same as those which could be identified by the present methods of claims 1, 16 and 28.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers April 5, 2004 CARLA J. MYERS
PRIMARY EXAMINER